	CO-ORDINATION OF NOTIFIED BODIES **PPE Regulation 2016/425** **RECOMMENDATION FOR USE**	PPE-R/00.071 Version 02

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Article: Article 26 Annex: Clause:

Key words:

sub-contracting, acceptance of test results, competence of laboratories, manufacturer, independent

Question:

May a notified body use test data produced by a manufacturer's test laboratory (this includes any laboratory not independent of the manufacturer)?

Solution:

Test data produced by a manufacturer's test laboratory cannot be considered independent and should not be used by a Notified Body in support of conformity assessment procedures. This includes situations when the manufacturer's test laboratory is ISO/IEC 17025 accredited. Whilst ISO/IEC 17025 ensures impartiality it does not ensure independence ("independence" was deleted from the 2017 version)(PPE Regulation article 24(3)).

It is recognised that there may be exceptional cases when there is no independent facility equipped to carry out certain tests. In such cases a Notified Body may utilise such facilities and their staff but shall assume full responsibility for all aspects of the testing performed. When doing so, the Notified Body should apply the relevant principles of ISO/IEC 17025 and shall maintain records to justify their use of such facilities and acceptance of test data.